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Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Ln., Rm. 1061
Rockville, Maryland 20857-0003

Reference: Docket No. 98N-1265

Dear FDA Representative In Receipt Of This Letter:

I hereby register my request that the MOU, as well as the Compounding Section 503A, of the Modernization Act be amended. In its present form, it severely restricts the rights of physicians and patients to obtain healthcare products from the provider(s) of their choice.

I am currently prescribed compounded tri-estrogens, plus progesterone, which can only be obtained from an out-of-state pharmacy. This compounded prescription is made up of natural estrogens and progesterone, which have completely eliminated the problems for which they were prescribed without the side effects I experienced with patented synthetic hormones first prescribed for me by my physician. There are approximately 5 other women with whom I work who are being prescribed the compounded hormones available to us only through Women's International Pharmacy. I hope that they, too, will register their desire to see this MOU/Compounding Section revised to allow us to continue to receive this treatment.

I believe this is a fundamental right of every American citizen to work with his physician to find the most effective treatment plan available. We are individuals with very different physical and psychological makeup. A "one size fits all" patented formula does not work for everyone. Pharmacological compounding, especially using natural substances more readily utilized by the human body rather than synthetic ingredients that cause unpleasant and/or dangerous side effects, is a very important option still available to us. It would be a serious infringement for our government to restrict this freedom in any way.

Thank you for your consideration.

Sincerely,

Linda Cummings

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